In re Application of Ulrich et al. -- 08/882,431

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

As requested by Examiner, the specification has been amended to include sequence identifyers for sequences in the originally filed application corresponding to the Sequence Listing as originally filed. Entry of amendments to the specification are respectfully requested.

Claim 1 has been amended to more clearly define the claimed invention. Support for the claim as amended is found throughout the specification and specifically in Example 8, pages 58 and 59 of the specification as originally filed. Entry of the amended claim is respectfully requested.

Claims 1, 4-6, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 are pending.

The disclosure stands objected to because the specification fails to reference or identify the SEQ ID NOS. disclosed in the sequence listing. The identity of each of the sequences in the specification has been added by amendment. Withdrawal of the objection is respectfully requested.

The specification stands objected to as failing to provide proper antecedent basis for the recombinant DNA constructs pETA489270C, pETB2360210, and pETB899445P claimed in claims 37-39 and claims 37-39 and in addition the claims are allegedly not enabled since the constructs do not appear

to be set forth in the specification and have not been shown to be publicly known and freely available.

With respect to the antecedent basis, the specification describes the cloning of the altered toxins A489270C, B2360210, and B899445P in Materials and Methods on page 32 under "Site-specific mutagenesis", and on page 21, lines 18-34, through page 22, lines 1-24. The plasmids used are also described, namely, pSE380 and pET21, both publicly available. A description of the vectors pSE380 and pET21 reproduced from a Novagen catalogue are provided for Examiner's perusal. Applicants submit that the description of the DNA inserted into the known and publicly available vectors in addition to the high skill of people in the art renders the plasmids enabled.

Furthermore, Applicants have deposited these vectors at the American Type Culture Collection on June 4, 1997, prior to the filing date of this application, i.e. June 25, 1997. A copy of deposit receipt is enclosed as proof of deposit. Therefore, in view of the above, pETA489270C, pETB2360210, and pETB899445P are enabled. Withdrawal of the objection and rejection is respectfully requested.

Claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter.

Applicants apologize for the inconsistencies in the previously submitted sequence listing and appreciate the opportunity to correct the inconsistencies.

A substitute sequence listing is submitted which has been corrected and now corresponds with the originally filed sequence listing. The undersigned hereby certifies that the computer and paper readable copies of the Sequence Listing are the same and do not contain new matter. Entry of the substitute Sequence Listing is respectfully requested.

Claims 1, 18, 43-44, 53, and 62 stand rejected under 35 U.S.C. 102(a) as allegedly anticipated by Bavari et al. (Vaccines 96).

Bavari et al. was published within one year of the filing date of this application and is the inventors' own. Attached for the Examiner's review is a copy of the front pages of the <u>Vaccines 96</u> book received by the library at Fort Detrick indicating a receipt date of September 17, 1996. The accompanying Declaration signed by the inventors verifies this information and is believed to remove this reference as prior art. As this article is not properly citable against the present application, reconsideration and withdrawal of the rejection are respectfully requested.

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Claims 1, 18, 43-44, 53, and 62 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Hayball et al. (International Immunology, 1994). This rejection is traversed in view of the claim amendment and the following.

Claim 1 as amended is drawn to a superantigen toxin with altered ability to bind to multiple subsets of T-cell receptors. Applicants have found that the binding of the mutant superantigen of the claimed invention was altered with respect to several distinct populations of T-cell receptors. Please see specification at Example 8, pages 58 and 59.

Hayball et al., on the other hand, found that the binding of their SEB mutant was altered with respect to only one subset of T-cell receptors (TCR), and the majority of TCR binding was not altered. See Hayball et al. at page 200, last paragraph of Introduction.

Therefore, due to the distinct difference between the claimed invention and Hayball et al., the claimed invention is not anticipated by Hayball et al. Reconsideration and withdrawal of the rejection are respectfully requested.

All objections and rejections have been addressed. This application is believed to be in condition for allowance, and Notice to that effect is respectfully solicited.

Respectfully submitted,

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ATTN: MCMR -JA (Charles H. Harris-Patent Atty)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to

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on the date of March 22, 1999.

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